

**REMARKS/ARGUMENTS**

Claims 16 and 17 are pending and amended by this Amendment. Reconsideration in view of the above amendments and the following remarks are respectfully requested.

Claims 16 and 17 were rejected under 35 U.S.C. §102(e) over Mellen (U.S. Patent Publication No. 2003/0114900). This rejection is respectfully traversed.

Claim 16 is directed to an electrostimulating apparatus that generates a relaxing sequence suitable for stimulating striated muscle fibre, based on three fundamental parameters: the width of the electric stimulation, the frequency of said stimulation and the intervals of time, wherein a plurality of width/frequency combinations follow, in said relaxing sequence a basic variation being the variation in frequency whereas widths remain constant.

Amended claim 16 defines an apparatus to generate a relaxing sequence, e.g., a so-called DCTR sequence, that is able to effectively stimulate striated muscle fibres, i.e. skeletal muscles. The present specification provides experimental data for this treatment (see paragraph [0036]-paragraph [0053], of the U.S. Publication of the subject application).

In particular, it has been found that the DCTR-type muscle relaxing sequence is able to closely emulate the action of a nerve fibre innervating a skeletal muscle, which effect is particularly advantageous when the sequence is used, e.g., for a decontracturing purpose.

Claim 17 is directed to an electrostimulating apparatus that generates a vasoactive sequence of activation of the microcirculation suitable for stimulating the smooth muscle fibre and the postsynaptic neuroreceptors, based on three fundamental parameters: the width of the electric stimulation, the frequency of said stimulation and the time wherein a plurality of combinations of width/frequency follow, said vasoactive sequence comprising three

subsequences, wherein a frequency increase is provided in the first and second subsequences and a variation of width is provided in the third subsequence.

Amended claim 17 defines an apparatus producing a vasoactive sequence, e.g., an ATMC sequence having a prevalent action on so-called “microcirculation”, i.e. the smooth sphincters of arterioles and venules of a subcutaneous layer.

Applicant has experimentally shown (see paragraph [0054] - paragraph [0077], of the U.S. Publication of the subject application) that, a sequence of vasodilatations and vasoconstrictions with sequential increases and decreases of the microcirculation haematic flow is produced.

This effect is achieved by the neuromodulation of the neurovegetative and sympathetic system, which affects vasoactivity through the smooth muscle of the smaller blood vessels.

In a series of further experimental tests, electrical stimulations including the vasoactive sequence have been associated with stimuli inducing vasodilatation or vasoconstriction, so that when the vasoactive sequence is accompanied by a stimulus able to induce vasodilatation - for example a thermal heating stimulation - the vasodilatation is enhanced by this association, whilst, when the vasoactive sequence is accompanied by a stimulus able to cause vasoconstriction - such as a thermal cooling stimulation - the association substantially enhances vasoconstriction.

The physiological effects disclosed above are achieved in view of the fact that the vasoactive sequence creates an effective neuromodulation, which is able to amplify the excitation phenomena of the primary and secondary neuroceptors.

A therapeutic application of the vasoactive sequence according to the invention of claim 17 includes the combination thereof with hyperthermic and/or cryotherapeutic treatments, for the purpose of enhancing the corresponding effects.

In this way, a localised neoplasia and a solid tumour can be treated by combining temperature effects with vasoactive effects. If cryotherapy is combined with the vasoactive sequence, the vasoconstrictive effects are increased, thereby producing localised hypoxia in a tumour mass with consequent necrosis of the latter. In an analogous manner, by combining the vasoactive sequence with a hyperthermic therapy, a vasodilatation is achieved that amplifies the necrotizing effect of the hyperthermia on a tumour mass.

The neurophysiological and medical tests performed by the Applicant, and disclosed in the Application in subject, substantially prove that the electrostimulating sequences, as defined in amended claims 16 and 17, have been achieved owing to the Applicant's scientific intuitions, properly supported by a rigorous experimental work.

Therefore, it is believed that the claimed relaxing and vasoactive sequences, and thus the electrostimulating apparatuses generating the latter, could not be achieved by a skilled person owing to an obvious combination of any technical teachings or suggestions findable in the cited prior art documents.

Claims 16 and 17 were rejected under 35 U.S.C. §102(e) over Mellen (U.S. Patent Publication No. 2003/0114900). This rejection is respectfully traversed.

Mellen does not teach or disclosure this subject matter. Mellen discloses an apparatus for applying electrical stimuli to a living body, including a pair of applicators 10. The electrical stimuli can be used for both stimulating skeletal muscles and inducing stronger vasoconstriction in blood vessels. Unlike prior art skin electrodes or needles, the applicators 10 generate a current flow in the patient's body, but do not cause current to flow directly from the applicator 10 into the body through the skin surface. The solution is achieved by providing an electrically insulating material between the skin and the electrically conductive material. The signals to be

produced by using the apparatus equipped with the applicators 10 demonstrates a duration (width) between 0.5 to 1 milliseconds and a frequency between 40-100 Hz (however, Mellen states that a preferred constant frequency is produced which is about 57 Hz).

Therefore, Mellen discloses an electrostimulating apparatus that generates a sequence suitable for stimulating striated muscle fibre, based on two parameters, i.e., the width of the electrical stimulation and the frequency of the stimulation. Accordingly, Mellen does not disclose or suggest a third parameter is involved, on which the sequence is based, i.e., the intervals of time wherein a plurality of width/frequency combinations follows. Mellen also does not disclose that, in the sequence, the frequency varies whereas the widths remain constant, as set forth in claim 16.

In regard to claim 17, as discussed above, Mellen discloses an electrostimulating apparatus that generates a sequence suitable for inducing stronger vasoconstriction in blood vessels, i.e., a vasoactive sequence, which is based on two parameters, i.e., the width of the electric stimulation and the frequency of the stimulation. Nevertheless, Mellen does not teach or suggest a third parameter is provided, on which the sequence is based, i.e., the time wherein a plurality of width/frequency combinations follow. Also, Mellen does not teach that the vasoactive sequence comprises three subsequences, wherein the frequency increase is provided in the first and second subsequences and a variation of width is provided in the third subsequence, as recited in claim 17.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 16 and 17 were rejected under 35 U.S.C. §102(b) over Mower (U.S. Patent No. 6,343,232). This rejection is respectfully traversed.

Mower discloses an apparatus and a method for stimulating muscle tissue by using biphasic waveforms that reduce the electrical energy required to elicit contraction.

The biphasic electrical stimulation disclosed in Mower comprises the following embodiments:

- A first anodal stimulation, followed by a second cathodal stimulation (Fig. 1);
- A first cathodal stimulation, followed by a second anodal stimulation (Fig. 2); and
- A series of anodal pulses, followed by a cathodal stimulation (Fig. 5).

Various embodiments of the stimulation are as follows:

- Anodal stimulation having a voltage < 3 V;
- Anodal stimulation having a duration (width) equal to 2-8 milliseconds;
- Cathodal stimulation having a voltage ranging between 3 and 20 V, or greater than 20 V;

and

- Cathodal stimulation having a duration (width) equal to 0.3-0.8 milliseconds, or less than 0.3 milliseconds.

However, Mower states that the stimulating method can be applied also to both striated muscle fibres and smooth muscle tissue (blood vessels). Therefore, Mower discloses an electrostimulating apparatus that generates a sequence suitable for stimulating striated muscle fibre, based on two parameters, i.e. the width of the electric stimulation and the intensity (voltage) of the stimulation.

Accordingly, Mower does not disclose that:

- A third parameter is provided, on which the sequence is based, i.e. the intervals of time wherein a plurality of width/frequency combinations follow; or that
  - In the sequence, the frequency varies whereas widths remain constant.

Amended claim 16 is thus novel over Mower.

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In regard to claim 17, Mower does not disclose that -

-A third parameter is provided, on which the sequence is based, i.e. the time wherein a plurality of width/frequency combinations follow; or that

-The vasoactive sequence comprises three subsequences, wherein a frequency increase is provided in the first and second subsequences and a variation of width is provided in the third subsequence.

Amended claim 17 is thus novel over Mower.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 16 and 17 were rejected under 35 U.S.C. §102(b) over Blanchard (U.S. Patent No. 3,897,789). This rejection is respectfully traversed.

Blanchard discloses an acupuncture apparatus, through which pulses of current can be supplied to an acupuncture needle by a pulse generator.

The train of pulses produced by the pulse generator are used for vibrating an acupuncture needle (as an alternative to the conventional manual vibration) in such a manner that the patient body's impedance does not affect the quality of the stimulation.

The pulse-width (duration), frequency and amplitude can be adjustably controlled, for example, the pulse-width may range between 0.5 and 100 milliseconds.

Therefore, Blanchard discloses an electrostimulating apparatus that generates trains of pulses, i.e. sequences, which may stimulate striated muscle fibre and having preset frequencies and pulse-widths.

Nevertheless, Blanchard does not discloses that:

-A third parameter is provided, on which the sequence is based, i.e. the intervals of time

wherein a plurality of width/frequency combinations follow; or that

-In the sequence, the frequency varies whereas widths remain constant.

Amended claim 16 is thus novel over Blanchard.

In regard to claim 17, Blanchard does not disclose a vasoactive sequence that is suitable for stimulating the smooth muscle fibre and the postsynaptic neuroreceptors, that is based on three fundamental parameters (the width of the electric stimulation, the frequency of the stimulation and the time wherein the plurality of combinations of width/frequency follow), or that comprises three subsequences, wherein a frequency increase is provided in the first and second subsequences and the variation of width is provided in the third subsequence. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 16 and 17 were rejected under 35 U.S.C. §102(b) over Maurer (U.S. Patent No. 4,431,002). This rejection is respectfully traversed.

Maurer discloses a transcutaneous electrical nerve stimulation (TENS) apparatus, comprising:

-An astable pulse generator, generating a first train of pulses at a selected repetition rate, the width of the pulses of the first train being varied over a predetermined range;

-A monostable pulse generator, receiving the first train of pulses and generating a second pulse train having the frequency of the first train;

-A further monostable pulse generator, which is connected to pulse amplifiers, receives the first and second train of pulses and thus delivers a supply pulse to the patient;

-Adjustable pulse modulators, which are connected to the second pulse generator and simultaneously increase the repetition rate of the first train of pulses and decrease the amplitude and pulse width of the second train of pulses.

The output voltage may range between 0 and 60 V, the width may range between 0 and 400 microseconds, the pulsing rate (frequency) may range between 1 to 100 pulses per second.

In particular, the frequency varies between two levels, the variation being accompanied by changes in the pulse width and amplitude.

Therefore, Maurer discloses an electrostimulating apparatus that generates a sequence suitable for stimulating striated muscle fibre, based on two parameters, i.e. the width of the electric stimulation and the frequency of the stimulation.

However, Maurer does not specify that, in the sequence, intervals of time are provided wherein a plurality of width/frequency combinations follow.

Moreover, Maurer does not disclose that, in the sequence, the frequency varies whereas widths remain constant.

Amended claim 16 is thus novel over Maurer.

In regard to independent claim 17, Maurer does not disclose a vasoactive sequence that is suitable for stimulating the smooth muscle fibre and the postsynaptic neuroreceptors, that is based on three fundamental parameters: the width of the electric stimulation, the frequency of the stimulation and the time wherein a plurality of combinations of width/frequency follow. Also, Maurer does not teach an apparatus including three subsequences, wherein the frequency increase is provided in the first and second subsequences and the variation of width is provided in the third subsequence.

Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

ZANELLA  
Appl. No. 10/550,601  
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The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4017-36.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_ /Paul T. Bowen/  
Paul T. Bowen  
Reg. No. 38,009

PTB:jck  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100